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TITLE: Short-Term Exercise and Prostate Cancer Prevention in African American Men

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14. ABSTRACT: This study seeks to examine the impact of exercise on serum factors related to prostate cancer in African-American men. Aims and Objectives: 1. To recruit 40 African-American men between the ages of 40 and 70 who are at increased risk for developing prostate cancer and randomize them into an exercise intervention or control group. 2. To examine the effect of 12 days of aerobic exercise over 4 weeks on PSA levels in African-American men who have PSA levels under 4.0 ng/ml. 3. To examine the effect of 12 days of aerobic exercise on free and total testosterone, insulin, IGF1, and SHBG levels in African-American men. A total of 40 African-American men between the ages of 40 – 70 yrs, from the Howard University Cancer Center prostate screening program that have a PSA under 4.0 ng/ml, a BMI > 25 and < 35 kg/m2, <375 pounds, and have been sedentary for at least 6 months (not exercising for more than 20 minutes 2 days a week). The men will be randomized into 2 groups 12 days of aerobic exercise (20 participants), or a control group (20 participants). The 12 days of exercise will consist of 30 minutes of walking on a treadmill at 50 – 60% of maximal heart rate reserve (HRR). Free testosterone, lipids, glucose, insulin, SHBG, psychosocial measures, body weight, BMI and body fat, anthropometric measurements, height, and weight will be measured before and after the study.

15. SUBJECT TERMS
Prostate Cancer Risk Reduction, African-American, Males

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Annual Report
Short-Term Exercise and Prostate Cancer Prevention in African-American Men

Proposal Log Number PC040735, Award Number W81XWH-05-1-0366, HSRRB Log Number A-13283

INTRODUCTION

Background:

African-American men have the highest incidence of prostate cancer in the world. The incidence of prostate cancer in African-American men is 59% greater than in Caucasian men. The exact cause for the increased incidence of prostate cancer in African-American is unknown. However, a diet high in fat and/or a sedentary lifestyle may predispose African-African men to prostate cancer by affecting levels of serum factors that potentate the growth of the cancer cells such as free testosterone, sex hormone-binding globulin (SHBG), insulin, insulin-like growth factor-1 (IGF1), prostate-specific antigen (PSA), and insulin-like growth factor binding proteins- 2 and 3.

Aims and Objectives:

1. To recruit 40 African-American men between the ages of 40 and 70 who are at increased risk for developing prostate cancer and randomize them into an exercise intervention or control group.
2. To examine the effect of 12 days of aerobic exercise over 4 weeks on PSA levels in African-American men who have PSA levels under 4.0 ng/ml.
3. To examine the effect of 12 days of aerobic exercise on free and total testosterone, insulin, IGF1, and SHBG levels in African-American men.

Hypothesis:

H1 Twelve days of exercise will reduce PSA levels in African-American men.
H2 Twelve days of exercise will reduce free and total testosterone levels in African-American men.
H3 Twelve days of exercise will reduce insulin levels in African-American men.
H4 Twelve days of exercise will increase SHBG levels of African-American men.

Study Design:

A total of 40 African-American men between the ages of 40 – 70 yrs, from the Howard University Cancer Center prostate screening program that have a PSA under 4.0 ng/ml, a BMI $\geq$ 25 and < 35 kg/m^2, <375 pounds, and have been sedentary for at least 6 months (not exercising for more than 20 minutes 2 days a week). The men will be randomized into 2 groups 12 days of aerobic exercise (20 participants), or a control group (20 participants). All participants will be screened by a physician for cardiovascular disease and will participate in a maximal graded exercise test. The 12 days of exercise will consist of 30 minutes of walking on a treadmill at 50 – 60% of maximal heart rate reserve (HRR). Blood samples will be taken in the morning after an overnight fast on day 2, and

day 16, 24 – 36 hours after the last bout of exercise. Serum will be separated from the blood and stored at -80˚C until analyzed. Free testosterone, lipids, glucose, insulin, SHBG, psychosocial measures, body weight, BMI and body fat, anthropometric measurements, height, and weight will be measured before and after the study.

BODY

1) KEY RESEARCH ACCOMPLISHMENTS

This study is still in the data collection phase. Therefore, no research findings are available for reporting to date.

2) STATEMENT OF WORK/TIME LINE

Months	Item	Status
Months 1-3	IRB Submission, revision and approval	Initial Review Completed – Renewal pending
	Study preparation (laboratory set-up/personnel selection)	Completed - Replacement of study physician
Months 3-20	Data Collection	In Progress/ 19 participants recruited to date
Months 20-24	Data Analysis/ Manuscript Development/Dissemination	Not yet initiated

REPORTABLE OUTCOMES

1) IRB UPDATE

IRB: IRB approval was obtained on February 2007 and is valid until February 2008.

2) ENROLLEMENT STATUS

Recruitment Strategies

HUCC Prostate Cancer Screening: A strong recruitment effort has been made to promote study enrollment. Our main source of recruitment has come from the Howard Cancer Center monthly prostate screenings. Study flyers were sent to men with PSA values < 4.0 ng/ml. Interested participants called the research office and were pre-screened and scheduled for appointments.

Physician Offices: Flyers were placed in HUH Family Practice, Oncology, and Radiology offices.

Churches: Study flyers were sent to area churches. Some churches included the study information in the Sunday bulletins. Flyers were also sent to church based cancer support groups.

Support Groups: Study flyers were sent to area cancer support groups.

Print Media: An advertisement for this study was placed in the Washington Post and the North West Current.

Health Fairs: This study was advertised at a number of health fairs. In particular, the study flyers were distributed at the Black Family Reunion (September, 2006). This event drew a large number of area African-American residents. Also, study flyers were distributed at the Channel 4 (NBC) "It's Your Health" event (2007). This health fair drew a large number of area residents as well. This study was also promoted at a number of church health fairs.

Prostate Screening Grant: The Howard University Cancer Center has encumbered external funds from the District of Columbia's Department of Health to screen 3,500 Afric an-American men for prostate cancer. This screening effort has attracted a large number of potential participants to this study.

Number of Men Pre-Screened:
A total of 162 men responded to our recruitment efforts. Of this number, 19 men were enrolled in the study. 11 men did not qualify due to PSA results outside the study range, 31 were physically active, 3 men were diagnosed with prostate cancer, 9 men had uncontrolled high blood pressure, 1 person had uncontrolled diabetes, 12 men did not know their PSA results, 1 person was recently had a hip replacement, 2 men were on PSA reducing medications, 1 person was on beta-blockers, 4 men did not meet the age requirements, 1 person did not meet the weight requirements, 3 men were no longer interested after being screened, 2 men could not participate due to conflicting schedules, 62 men were not able to be reached by telephone after several attempts.

Number of Men Enrolled:
A total of 36 participants have been enrolled and consented to date. Nineteen participants have successfully completed the study. Nine of these participants have been placed in the exercise intervention group and ten have been placed in the control group.

3) Research Progress

Data collection is still in progress. Therefore, no results are available for reporting.

4) Amendments

The following study amendments have been submitted to Howard University IRB. These amendments were submitted to Howard University IRB in January 2007. Approval for these amendments are expected to be granted mid-February 2007. The PI requests the approval of these amendments from the Department of Defense as well.

1. **Personnel Change:**

Dr. Peter Gaskin (pediatric cardiologist/ Howard University Hospital) is no longer on faculty at Howard University Hospital. Therefore, Dr. Emeka Ihemelandu will replace Dr. Gaskin and will serve as the physician overseeing the graded exercise testing.

2. **Flyer**

We have changed the contact number on the flyer to reflect Ms. Jennifer Sween's office number.

5) Adverse Events/Complaints/Deviations

No adverse events, complaints or deviations have been made regarding this protocol.

CONCLUSION

The effect of exercise on serum factors that increase the risk of prostate cancer has never been examined in AA men. Some studies have reported leisure-time physical activity levels in blacks ages 35 – 74 to be significantly lower than whites of similar age. It has been suggested that a high fat diet and sedentary lifestyle may possibly cause the increased incidence of prostate cancer in AA men. The results of this study have the potential to provide essential and practical recommendations for lifestyle interventions.